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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,833	10/24/2003	Marcel Limousin	8707-2165	1007
7590	06/16/2006		EXAMINER	
Orrick, Herrington & Sutcliffe LLP 666 Fifth Avenue New York, NY 10103			SMITH, STEPHANIE R	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/693,833

Applicant(s)

LIMOUSIN ET AL.

Examiner

Stephanie Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>24 October 2003</u> ; <u>March 2004</u> | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/693833, filed on October 24, 2003.

### ***Information Disclosure Statement***

The information disclosure statement filed on March 1, 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because foreign reference EP 0 970 713 A1 does not have an English translation. It has been placed in the application file, but the information referred to within EP 0 970 713 A1 has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Street et al (EP 1 151 718 A2). Referring to claim 1, Street et al. teach an implantable monitor that senses one or more physiologic signals to identify breathing patterns. The physiological signals are processed to generate respiratory rate, respiratory tidal volume, heart rate, or arterial oxygen saturation. The physiologic parameter data are analyzed to derive an indication of periodic breathing and to determine cycles of hypopnic breathing within a periodic breathing episode (see columns 4 and 5, paragraph 19), with the periodic breathing episode itself being apnea. Street et al. further teach that an intracardiac electrogram can be sensed, and heartbeat R-R intervals are calculated, and changes in the frequency of the power spectrum of the signals are used to indicate periodic breathing (see column 6, paragraph 24). Street et al. additionally teach that the status of a patient with chronic heart failure is monitored to optimize patient therapy and to recognize and facilitate the early termination of a developing exacerbation (see column 4, paragraphs 16-17). Referring to claims 2 and 3, Street et al. teach that the contractility variation is analyzed before and after detection of hypopnea (see figure 2). Referring to claim 4, Street et al. teach measuring intrathoracic impedance, and that it can be measured between two cardiac electrodes

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(see columns 4 and 5, paragraph 14 and paragraph 19). Regarding claim 5, Street et al. teach that an electrogram signal is sensed from a sensing electrode, and R-R intervals are calculated and a power spectrum analysis is performed. Changes in the very low frequency component of a power spectrum of R-R intervals are used to indicate periodic breathing (see column 6, paragraph 24).

With reference to claims 11-13, the apparatus detects cyclic behavior in any of the four physiologic parameters with simple comparisons of present value to programmed thresholds. Thresholds are determined as percentages of the long-term average for that measure (see figure 2 and column 7, paragraph 29).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Street et al. in view of Hartley et al (U.S. 6161042). Street et al. teach the apparatus described above, but do not teach modifying the parameter to a second value or restoring the operating value to the first parameter when the analysis means no longer detects a variation. With regards to claims 6, Hartley et al. teach that the minute ventilation short term and long term averages are calculated and compared by subtracting the long term average from the short term average. The difference is optionally scaled and used to adjust the pacing rate by increasing it when the short term average exceeds the long term average (see column 16, lines 20-25). Further, with reference to claim 7, Hartley et al. teach a lower rate limit to which the incremental sensor driven rate is added, and that the minute ventilation indicated rate is the rate at which pacing is delivered. If the value of the short term average is less than the value of the long term average, pacing therapy is delivered at the lower rate limit (see column 16, lines 30-39). Further, Hartley et al. teach that the minute ventilation is calculated from the transthoracic impedance (see column 6, lines 30-34). Hartley et al. teach that this adjustment of the pacing rate effectively manages the patient's heart rate based on an accurate indication of metabolic need (see column 4, lines 37-38). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was disclosed to combine the apparatus taught by Street et al. with the adjustment of

pacing rate based upon minute ventilation as taught by Hartley et al. in order to effectively manage the patient's heart rate based on an accurate indication of metabolic need.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Street et al. in view of Bonnet (U.S. 6574507). Street et al. teach the apparatus described above, but do not teach an increase in response to a detected variation and a detected apnea. Bonnet teaches applying an increased cardiac stimulation rate in the event of a detection of an apnea (see column 3, lines 1-3). Bonnet further teaches that apnea is determined in response to a measured respiratory signal that includes a minute ventilation sensor (see column 2, lines 64-66 and column 3, lines 5-6) and further that the minute ventilation parameter is obtained by a measurement of the intrathoracic impedance (see column 4, lines 1-5). Bonnet teaches that increasing the stimulation frequency accelerates the frequency of the myocardium to compensate for the effects of the apnea (see column 8, lines 66-67 and column 9, lines 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was disclosed to combine the apparatus for treating apnea or hypopnea as taught by Street et al. with the increase in frequency stimulation taught by Bonnet in order to accelerate the frequency of the myocardium to compensate for the effects of the apnea.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Street et al. Street et al. disclose the claimed invention except for the shortened atrio-ventricular delay and multisite pacing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus for

treating apnea or hypopnea as taught by Street et al, with a shortened atrio-ventricular delay and multisite pacing since it was known that shortening the atrio-ventricular delay will provide increased metabolic need when the patient requires it and multisite pacing provides a more coordinate therapy to increase cardiac output and treat abnormal cardiac activity.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. 2003/0195571 to Burnes et al. discloses an apparatus for treating sleep apnea that produces a stimulating pulse when a sleep apnea interruption occurs.

U.S. 6459929 to Hopper et al. disclose an apparatus for providing congestive heart failure status that measures transthoracic impedance to obtain an estimate of minute ventilation, respiratory rate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Smith whose telephone number is 571-272-2834. The examiner can normally be reached on Monday-Friday between 7:30 am-4:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRS 6/12/2006  
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GEORGE R. EVANSKO  
PRIMARY EXAMINER  
6/12/6